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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,169	02/11/2004	Michael E. Burczynski	AM101080	1858

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WYETH LLC  
PATENT LAW GROUP  
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MADISON, NJ 07940

EXAMINER
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HIBBERT, CATHERINE S

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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01/06/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/775,169	<b>Applicant(s)</b> BURCZYNSKI ET AL.	
	<b>Examiner</b> CATHERINE HIBBERT	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,7,9,17-24,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9, 17, 21-24 and 26-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' Amendments to the Claims filed 21 September 2009 have been received and entered. Claims 2-5, 8, 10-16 and 25 are cancelled. Claims 1, 6-7, 9, 17-24 and 26-27 are pending. Claims 6 and 18-20 are withdrawn. Claims 1, 7, 9, 17, 21-24 and 26-27 are under examination in this Office Action.

### ***Response to Arguments***

Any objections/rejections not repeated in this action are withdrawn herein.

The rejection of Claims 7, 17, 24 and 26-27 under 35 U.S.C. 112, second paragraph, is WITHDRAWN based on claim amendments. The rejection of cancelled Claim 10 is moot.

The rejection of Claims 1, 7, 9, 17, 21-24 and 26-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn based on Applicants persuasive argument. The rejection of cancelled claim 10 is moot.

The rejection of Claim 1 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21 and 34 of copending Application No. 10/793,032 is WITHDRAWN based on claim amendments in the '032 application. It is noted that the genes in Table 1 of the conflicting '032 application (currently being issued as US Patent No. 7,643,943), are not disclosed in the instant parent application 10/775,169. The rejection of cancelled Claim 10 is moot.

***New grounds of rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 9, 17, 21-24 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base Claims 1 and 17 are incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the one or more patients before CCI-779 treatment required for the reference expression profile are not required to be patients having RCC and thus the correlation to the expression profile of the samples obtained from the patient having RCC at a stage of treatment with CCI-779 is unclear.

Dependent Claims 7, 9, 21-24 and 26-27 are indefinite insofar as they depend from base Claims 1 and 17.

Additionally, Claim 24 recites the limitation "said patient" in line 3. There is insufficient antecedent basis for this limitation in the claim because Claim 17, from which Claim 24 depends, recites "a patient" in line 3 and recites "one or more patients" in line 10 and it is unclear which "patient" is encompassed by the limitation in Claim 24.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT, whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636  
Respectfully submitted,

Catherine Hibbert  
Examiner AU1636